MAR 1 2 2014

14 510(k) Summary

SPONSOR'S NAME & ADDRESS

Biosense Webster, Inc.
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Diamond Bar, CA 91765

OFFICIAL CORRESPONDENT

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SUBMISSION DATE

February 6, 2014

TRADE NAME

SOUNDSTAR® *eco* DIAGNOSTIC ULTRASOUND CATHETER

(Part Number: M-5723-17 / Catalogue Number: 10439011, Compatible with Siemens Ultrasound systems)

SOUNDSTAR® *eco* DIAGNOSTIC ULTRASOUND CATHETER

(Part Number: M-5723-18 / Catalogue Number: 10439236, Compatible with GE Ultrasound systems)

COMMON NAME

Electrophysiology Mapping/Ultrasound Catheter

CLASSIFICATION NAME/PRODUCT CODE

Intravascular Ultrasound Catheter/OBJ

CLASSIFICATION

Class II, 21 CFR 870.1200

PREDICATE DEVICE

The modified SOUNDSTAR *eco*8F and SOUNDSTAR *eco*F G Catheters are substantially equivalent to:

- SOUNDSTAR *eco* 10F P/N:M-5276-17 / Catalogue number 10439011 and SOUNDSTAR *eco* 10FG P/N:M-5276-17 / Catalogue number 10439011.

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- AcuNav 8F P/N M-5723-09 / Catalogue number 10135936 and AcuNav 8FG P/N M-5723-07 / Catalogue number 10135910.

DESCRIPTION OF MODIFIED DEVICE

The modified SOUNDSTAR *eco* 8F and SOUNDSTAR *eco* 8F G Catheters are both 90 cm long and 8F in diameter. They are IntraCardiac Echo (ICE) Catheters with acoustic array and magnetic location sensor equivalent to the currently cleared SOUNDSTAR *eco* 10F and SOUNDSTAR *eco* 10FG Catheters. The magnetic location sensor (providing location information to the CARTO 3 EP Navigation System Version 2.3 and 3.2) and an ultrasound transducer (acquiring real time ultrasound images) are embedded in the catheter tip.

The modified SOUNDSTAR *eco* 8F and SOUNDSTAR *eco* 8F G Catheters have a bifurcated 'tail' originating from the catheter handle which is identical to the bifurcated tail of the predicate device; the SOUNDSTAR *eco* 10F. One leg terminates in the SOUNDSTAR Flex Tab connector, which connects via the appropriate SWIFTLINK cable, to the appropriate Ultrasound system. Specifically, for the SOUNDSTAR *eco* Catheter 8F, the SWIFTLINK cable connects to the ACUSON Cypress™, the Acuson Sequoia™ or the ACUSON X300™ and Acuson SC2000™ Ultrasound systems. For the SOUNDSTAR *eco* 8F G Catheter, the SWIFTLINK cable connects to Vivid i and Vivid q Ultrasound systems.

Both versions of SOUNDSTAR *eco* 8F and SOUNDSTAR *eco* 8F G Catheters are based on the existing SOUNDSTAR *eco* 10F and SOUNDSTAR *eco* 10FG catheters and have the same intended use and clinical applications. The predicate and modified catheters share the majority of components and manufacturing process as explained previously.

The modified SOUNDSTAR *eco* 8F and SOUNDSTAR *eco* 8F G Catheters, when connected to the corresponding Ultrasound Systems, will provide real-time integration of ultrasound images with CARTO 3 Version 2.3 and Version 3.2 electromagnetic acquired maps.

INDICATIONS FOR USE

The Biosense Webster SOUNDSTAR® *eco* Diagnostic Ultrasound Catheter and related accessory devices are indicated for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart. When used with compatible CARTO® 3 EP Navigation Systems, the SOUNDSTAR® *eco* Catheter provides location information.
Please refer to the Compatibility Matrix Insert for Compatible CARTO® 3 Systems as each catheter is compatible with a specific version of CARTO® 3 and is not backwards compatible with previous versions of CARTO® 3 EP Navigation Systems.

DESCRIPTION OF MODIFICATION

The modifications to the predicate devices are:

1. A smaller diameter for the catheter body shaft. Consequently a smaller French size. Therefore change from 10 French to 8 French.

2. Change in the sensor design
The magnetic sensor in the predicate devices; SOUNDSTAR® *eco* 10F, SOUNDSTAR® *eco* 10FG catheters had a diameter of 1.3mm. The sensor used in the modified devices is a smaller sensor; magnetic sensor of 1.0mm, to allow the new sensor to fit in the smaller catheter body. In both catheters the Electromagnetic (EM) sensor enables accurate magnetic navigation for electro-anatomical mapping.

SOUNDSTAR *eco* 10F and SOUNDSTAR *eco* 10F G catheters sensor contains 3 coils in three X, Y, and Z axis. The coils have Ferrite core inside them and are assembled orthogonally with each other.
The coils have been repositioned for SOUNDSTAR® *eco* 8F catheter in comparison to the SOUNDSTAR® *eco* 10F catheters. Basically, the ferrites inside the coils of the SOUNDSTAR *eco* 8F and SOUNDSTAR *eco* 8F G catheters sensor have been replaced by air cores and assembled orthogonally.
The replacement of the ferrites by air cores in the sensor will allow the catheters to be used in the Stereotaxis Niobe® environment.
The main differences between the sensors are in the design and manufacturing process, while the end product is equivalent in functionality and performance

3. The SOUNDSTAR® *eco* 8F Catheters will be able to generate ultrasound images within the Stereotaxis NIOBE® Remote Magnetic System without impacting the location or image quality. For the catheter functionality, as mentioned above, the coils located inside of the sensor have been repositioned and the existing ferrites have been removed and replaced by air cores to allow the catheter to be used in the Sterotaxis Niobe® environment. The sensor material remains the same.

SUMMARY OF NONCLINICAL TESTS

To support the design change of the catheter, Design Verification Testing was performed on the modified SOUNDSTAR *eco*8F and SOUNDSTAR *eco* 8F G Catheters.

Safety and Electromagnetic Compliance testing was also performed to support the design changes on the predicate device. The Safety and Electromagnetic compliance testing validates the use of the modified devices; the SOUNDSTAR *eco* 8F and SOUNDSTAR *eco* 8F G Catheters with all the validated Siemens and GE Ultrasound systems.

The modified catheters are compatible with SOUNDSTAR *eco* Extension Cable and the CARTO 3 version 2.3 and 3.2 EP Navigation system. This compatibility has been documented by a Letter to file, filed on December 10, 2013.

SUBSTANTIAL EQUIVALENCE CONCLUSION

SIMILARITIES TO THE PREDICATE DEVICES

a) The modified SOUNDSTAR *eco* 8F and SOUNDSTAR *eco*8F G Catheters are ***identical*** to the currently cleared SOUNDSTAR *eco* 10F and SOUNDSTAR *eco* 10FG Catheters in the following aspects:

- Have the same intended use
- Use the same operating principle
- Are manufactured in the same manufacturing facility
- Use the same fundamental scientific technology
- Incorporate the same materials and construction
- Have the same deflection mechanism
- The magnetic sensor has the same material and location
- Have the same Ultrasound connections (to both Siemens and GE Ultrasound systems)
- Catheter body & strain relief have identical assembly process
- Have the same 64-channel acoustic phased array
- Have the same acoustic array location and connection
- Have the same packaging and are packaged using the same materials and processes
- Have the same Electronics; the PCB is inside the Hypertronic connector and Extension Cable
- Identical magnetic sensor location (not connected to the Printed Circuit Board (PCB))
- Identical handle, magnetic location sensor wires and connections
- Have the same handle material
- Have the same Steering mechanism
- Have identical Hypertronic connector
- Most of the manufacturing processes are identical
- Have the same shelf life
- Use the same sterilization method (EtO sterilization)
- Are single use devices

b) The modified SOUNDSTAR *eco* 8F and SOUNDSTAR *eco* 8F G Catheters are ***identical*** to the currently cleared AcuNav 8F and AcuNav 8FG catheters in the following aspects

- Have the same shaft material, color and process with a 90cm useable length

- The product functional specification (hi pot, acoustic, articulation) and the DVT criteria is identical
- Have the same strain relief material, composition and mechanical design

DIFFERENCES FROM THE PREDICATE DEVICES

a) The modified SOUNDSTAR *eco*8F and SOUNDSTAR *eco*8FG Catheters are ***different*** from the currently cleared SNDSTR10 and SNDSTR10G Catheters in the following aspects:

- Have different Tip dimensions
- Have a smaller French size for the catheter body shaft. Change from 10French to 8French diameter
- A smaller sensor to fit in a smaller diameter of shaft.
- The SOUNDSTAR *eco* 8F catheters will be able to generate ultrasound images within the Stereotaxis NIOBE® Remote Magnetic System, without impacting the location or image quality.
- The labels, IFUs and Matrices are slightly modified
- The handle color is blue

c) The modified SOUNDSTAR *eco* 8F and SOUNDSTAR *eco* 8F G Catheters are ***different*** to the currently cleared AcuNav 8F and AcuNav 8FG catheters in the following aspects

- The last .5 cm of the shaft distal end out of 90 cm of the entire shaft length has additional internal grove to accommodate the sensor. The product functional specifications (hi pot, acoustic, articulation, length, OD, ID, Shaft Material) and the DVT criteria do not change despite of this change.
- The strain relief color is black
- Has the new Heat Shrink Tube shown at figure 5 on page 19 as the item F.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 12, 2014

Biosense Webster
Marina Guevrekian
Senior Specialist Regulatory Affairs
3333 Diamond Canyon Rd.
Diamond Bar, CA 91765 US

Re: K140318
Trade/Device Name: Soundstar ECO 8FG Ultrasound Catheter, Soundstar ECO 8F Ultrasound Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Intravascular Ultrasound Catheter
Regulatory Class: II
Product Code: OBJ
Dated: February 6, 2014
Received: February 10, 2014

Dear Marina Guevrekian,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems

(QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Linda J. Ricci -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

6 INDICATIONS FOR USE

510(k) No (if known): TBD

Device Name:
SOUNDSTAR *eco* 8F Catheter
SOUNDSTAR *eco* 8F G Catheter

Indications for Use:
The Biosense Webster SOUNDSTAR® *eco* Diagnostic Ultrasound Catheter and related accessory devices are indicated for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart. When used with compatible CARTO® 3 EP Navigation Systems, the SOUNDSTAR® *eco* Catheter provides location information.
Please refer to the Compatibility Matrix Insert for Compatible CARTO® 3 Systems as each catheter is compatible with a specific version of CARTO® 3 and is not backwards compatible with previous versions of CARTO® 3 EP Navigation Systems.

Prescription Use (Part 21 CFR 801 Subpart D) √ AND/OR Over-The-Counter Use (21 CFR 801 Subpart C) _____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Linda J. Ricci -S

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